

REMARKS

This responds to the Office Action dated April 15, 2003. No claims are amended or cancelled. Claims 71-75 are added. As a result, claims 41-75 are now pending in this patent application.

For brevity, Applicant reiterates the arguments previously made of record in Applicant's January 16, 2003 Response to the October 16, 2002 Office Action. Those arguments are incorporated herein by reference, including Applicant's reservation of rights to swear behind certain references. This Response addresses the rejections in the April 15, 2003 Office Action.

§102 Rejection of the Claims

Claims 63 and 66 were rejected under 35 U.S.C. § 102(b) for anticipation by Struble et al. (U.S. Patent No. 6,081,748). Applicant respectfully traverses. Applicant can find no disclosure in the cited portions of Strubel et al. of disposing a first electrode in association with a left ventricular region of a heart, disposing a second electrode in association with a right ventricular region of the heart, and delivering a first pacing pulse between such first and second electrodes. The rejection states:

Strubel et al. disclose synchronous pacing of the two lower heart chambers (right and left ventricles) utilizing pacing/sensing electrodes (col. 1, lines 19-25 and col. 6, lines 14-58). The claimed method steps are inherently performed during synchronous pacing of right and left ventricles.

(Office Action at 2.) However, Applicant respectfully disagrees with any assertion that the claimed method acts are inherent to synchronous pacing of right and left ventricles.

For example, FIG. 3 of Strubel et al. apparently depicts a bi-ventricular pacing system. FIG. 3 includes a bipolar right ventricular pacing lead 32, which includes a right ventricular tip electrode 40 and a right ventricular ring electrode 38. FIG. 3 also includes a bipolar left ventricular (coronary sinus) pacing lead 42, which includes a left ventricular (coronary sinus) distal ring electrode 50 and left atrial (coronary sinus) proximal ring electrode 48. (See Strubel et al. at column 13, lines 58 – 67.) Strubel et al. apparently delivers pace pulses either between the right ventricular electrodes 38 and 40, or, alternatively, such pace pulses are delivered between the left ventricular electrodes 48 and 50. (See *id.* at column 14, lines 13-15 and lines 51-53.) In sum, Applicant can find no disclosure in the cited portions of Strubel et al. of

delivering a pace pulse between a right ventricular electrode and a left ventricular electrode, as recited or incorporated in claims 63 and 66. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

§103 Rejection of the Claims

1. Claim 57 was rejected under 35 U.S.C. § 103(a) for obviousness over Alt et al. (U.S. Patent No. 6,370,427). Applicant respectfully traverses. The rejection states:

Alt et al. disclose a method of pacing a heart with a first electrode 73 in a left ventricular region of the heart and a second electrode 64 in the right atrial region of the heart (col. 10, lines 8-17 and lines 54-57). Although Alt et al. do not disclose a first pacing pulse between the first electrode 73 and second electrode 64, it would have been an obvious matter of design choice to have delivered a first pacing pulse between the first electrode 73 and the second electrode 64, since applicant has not disclosed that the claimed method steps solves any particular problem and it appears that the invention would perform equally well with the method steps disclosed by Alt et al.

(Office Action at 2-3.) However, the cited portion of Alt et al. apparently uses bipolar electrodes. (*See* Alt et al. at column 9, lines 34-35.) One of ordinary skill in the art would recognize that a bipolar electrode refers to a closely-spaced pair of electrodes, with the bipolar electrode pair operating as anode and cathode to deliver a pacing pulse (and produce a resulting localized electric field) therebetween. Therefore, Applicant respectfully submits that the respective electric field “vector” between a bipolar anode and cathode in the right atrium, and the “vector” between a bipolar anode and cathode in the left ventricle will be substantially different than the electric field “vector” between a left ventricular electrode and a right atrial electrode, as recited or incorporated in the present claim 57. More particularly, the electric field of the latter arrangement will encompass and capture a different mass of cardiac tissue than the former arrangement. Therefore, the latter arrangement is more desirable than the former arrangement for patients having cardiac conduction abnormalities or other physiological conditions involving cardiac tissue that would be captured by the latter arrangement, but not by the former arrangement. Because the differences between the present claim and Alt et al. have such clinically significant implications, Applicant respectfully submits that claim 57 is not obvious over the cited portions of Alt et al. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of claim 57.

2. Claims 41, 42, 44, 45, 47 and 58 – 60 were rejected under 35 U.S.C. § 103(a) for obviousness over Alt et al. and Joseph (U.S. Patent No. 4,248,238). Applicant respectfully traverses. The Examiner's burden of establishing a *prima facie* case of obviousness requires, among other things, that each and every one of the recited claim limitations are taught or suggested in the cited prior art reference(s) independent of the teaching in the applicant's disclosure. *See In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); M.P.E.P. § 2142.

However, for the reasons discussed above with respect to claim 57 and Alt et al., Applicant can find no disclosure, teaching, or suggestion in Alt et al. and/or Joseph of delivering a pacing pulse between (1) a right atrial electrode and (2) at least two left ventricular electrodes, as recited or incorporated in claims 41, 42, 44, 45, 47 and 58 – 60. Moreover, as explained above, this difference is clinically significant because the resulting electric field will encompass and capture a different mass of cardiac tissue than Alt et al. and/or Joseph. Therefore, the claimed electrode arrangement will be more suitable for patients having conduction abnormalities or other physiological conditions involving cardiac tissue encompassed by the electric field resulting from pacing using this claimed electrode arrangement.

Furthermore, as expressly recognized in the rejection, Joseph apparently uses a second ventricular electrode merely as a backup for a first ventricular electrode, rather than for use together with the first ventricular electrode against a right atrial electrode. (*See* Office Action at 3; *see also* Joseph at column 5, lines 14-18). Therefore, by merely using the second ventricular electrode as a backup alternative to the first ventricular electrode, Joseph actually teaches away from using two ventricular electrodes together against a right atrial electrode.

Because no *prima facie* case of obviousness presently exists with respect to Joseph and/or Alt, and further because Joseph actually teaches away from the claim language, Applicant respectfully requests withdrawal of this basis of rejection of claims 41, 42, 44, 45, 47 and 58 – 60.

3. Claims 43 and 46 were rejected under 35 U.S.C. § 103(a) for obviousness over Alt et al. and Joseph, as applied to claim 41, and further in view of Callaghan et al. (U.S. Patent No. 4,858,610). Applicant respectfully traverses. The Examiner's burden of establishing a *prima facie* case of obviousness requires, among other things, that each and every one of the recited

claim limitations are taught or suggested in the cited prior art reference(s) independent of the teaching in the applicant's disclosure. *See In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); M.P.E.P. § 2142.

However, for the reasons discussed above with respect to claims 57 and 41, Applicant can find no disclosure, teaching, or suggestion, in Alt et al. and/or Joseph and/or Callaghan et al. of delivering a pacing pulse between (1) a right atrial electrode and (2) at least two left ventricular electrodes, as incorporated in claims 43 and 46 by their dependencies from claim 41. Therefore, no *prima facie* case of obviousness exists with respect to claims 43 and 46.

Moreover, regarding claim 46, Applicant can find no disclosure, teaching, or suggestion in these references of connecting a right ventricular electrode in common with a housing of an implantable pulse generator. Instead, Callaghan et al. apparently teaches away from such a common connection because the cited portion of Callaghan et al. refers to using the housing as a reference electrode for an electrode that is located in the heart chamber. By contrast, the present claims refer to using a housing that is commonly connected to a right ventricular electrode. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of claims 43 and 46.

4. Claims 48, 49, 54, 64 and 65 were rejected under 35 U.S.C. § 103(a) for obviousness over Struble et al. in view of Joseph. Applicant respectfully traverses. The Examiner's burden of establishing a *prima facie* case of obviousness requires, among other things, that each and every one of the recited claim limitations are taught or suggested in the cited prior art reference(s) independent of the teaching in the applicant's disclosure. *See In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); M.P.E.P. § 2142.

However, as discussed above with respect to the rejection under § 102 of claims 63 and 66, Applicant can find no disclosure, teaching, or suggestion in Struble et al. and/or Joseph of delivering a pace pulse between (1) a right ventricular electrode and (2) left ventricular electrodes. Instead, as discussed above, Struble et al. apparently uses bipolar electrodes, thereby obtaining a substantially different (more localized) electric field distribution than the configuration of claims 48, 49, 54, 64 and 65. As a result, the pacing electric field of Struble et al. may fail to capture cardiac tissue mass that, by contrast, would be captured by the presently claimed configuration.

Moreover, as discussed above with respect to the § 103 rejection of claims 41, 42, 44, 45, 47 and 58 – 60 using Alt et al. and Joseph, by merely using the second ventricular electrode as a backup alternative to the first ventricular electrode, Joseph actually teaches away from using two left ventricular electrodes together against a right ventricular electrode. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of claims 48, 49, 54, 64 and 65.

5. Claim 50 was rejected under 35 U.S.C. § 103(a) for obviousness over Struble et al. in view of Joseph, as applied to claim 48, further in view of Callaghan et al. Applicant respectfully traverses. The Examiner's burden of establishing a *prima facie* case of obviousness requires, among other things, that each and every one of the recited claim limitations are taught or suggested in the cited prior art reference(s) independent of the teaching in the applicant's disclosure. *See In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); M.P.E.P. § 2142.

However, as discussed above with respect to the rejection under § 102 of claims 63 and 66, Applicant can find no disclosure, teaching, or suggestion in the cited portions of Struble et al. and/or Joseph and/or Callaghan et al. of delivering a pace pulse between (1) a right ventricular electrode and (2) left ventricular electrodes. Instead, as discussed above, Struble et al. apparently uses closely bipolar electrodes located within the same heart chamber, thereby obtaining a substantially different (more localized) electric field distribution than the presently claimed configuration. As a result, the pacing electric field of Struble et al. may fail to capture cardiac tissue that, by contrast, would be captured by the configuration recited in claim 50. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of claim 50.

6. Claims 55, 56, 69 and 70 were rejected under 35 U.S.C. § 103(a) for obviousness over Alt et al. in view of Thong et al. (U.S. Patent No. 6,341,234). Applicant respectfully traverses. The Examiner's burden of establishing a *prima facie* case of obviousness requires, among other things, that each and every one of the recited claim limitations are taught or suggested in the cited prior art reference(s) independent of the teaching in the applicant's disclosure. *See In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); M.P.E.P. § 2142.

However, Applicant can find no teaching or suggestion in the cited portions of Alt et al. and/or Thong et al. of delivering a pacing pulse from a cathodic first ventricular defibrillation electrode to an anodic first ventricular pacing/sensing electrode, as recited or incorporated in

claims 55 and 56. Indeed, Applicant can find no teaching or suggestion in the cited portions of these references of using a ventricular defibrillation electrode as a cathode for a pacing pulse. Instead, the cited portion of Thong et al. apparently discloses only that a bipolar lead includes both anodic and cathodic electrodes. (*See* Thong et al. at column 5, lines 1-5). Because no *prima facie* case of obviousness exists with respect to these claims, Applicant respectfully requests withdrawal of this rejection.

Moreover, Applicant notes that these arguments were previously made of record in Applicant's January 16, 2003 Response to the October 16, 2002 Office Action. However, Applicant can find no answer in the present Office Action to these previous arguments of record. "Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it." MPEP § 707.07(f). Accordingly, Applicant respectfully requests withdrawal of this rejection of claims 55 and 56, or further clarification in the next official communication of the basis for maintaining the rejection.

Regarding claims 69 and 70, Applicant can find no teaching or suggestion in the cited portions of Alt et al. and/or Thong et al. of delivering a pacing pulse between a cathodic first electrode at a ventricular apex and a more proximal anodic second electrode. Instead the cited portion Thong et al. apparently discloses only that a bipolar lead includes both anodic and cathodic electrodes. (*See* Thong et al. at column 5, lines 1-5). Because no *prima facie* case of obviousness exists with respect to these claims, Applicant respectfully requests withdrawal of this rejection.

7. Claim 67 was rejected under 35 U.S.C. § 103(a) for obviousness over Struble et al. in view of Callaghan et al. Applicant respectfully traverses. The Examiner's burden of establishing a *prima facie* case of obviousness requires, among other things, that each and every one of the recited claim limitations are taught or suggested in the cited prior art reference(s) independent of the teaching in the applicant's disclosure. *See In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); M.P.E.P. § 2142.

Applicant can find no disclosure, teaching, or suggestion, in the cited portions of Struble et al. and/or Callaghan et al. and/or the cited portions of the other references relied upon for the other grounds of rejection of delivering a pace pulse between a left ventricular electrode and a

right ventricular electrode, as incorporated in claim 67 by its dependency on claim 63.

Accordingly, because no *prima facie* case of obviousness exists with respect to claim 67,

Applicant respectfully requests withdrawal of this basis of rejection.

8. Claim 68 was rejected under 35 U.S.C. § 103(a) for obviousness over Struble et al. in view of Callaghan et al., as applied to claim 67 above, and further in view of Joseph. Applicant respectfully traverses. The Examiner's burden of establishing a *prima facie* case of obviousness requires, among other things, that each and every one of the recited claim limitations are taught or suggested in the cited prior art reference(s) independent of the teaching in the applicant's disclosure. *See In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); M.P.E.P. § 2142.

As discussed above with respect to claim 67, Applicant can find no disclosure, teaching, or suggestion, in the cited portions of Struble et al. and/or Callaghan et al. and/or Joseph (and/or the cited portions of the other references relied upon for the other grounds of rejection) of delivering a pace pulse between a left ventricular electrode and a right ventricular electrode, as incorporated in claim 68 by its dependency on claim 63. Accordingly, because no *prima facie* case of obviousness exists with respect to claim 68, Applicant respectfully requests withdrawal of this basis of rejection.

Allowable Subject Matter and New Claims

Claims 51 – 53, 61 and 62 were indicated to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Accordingly, Applicant has added new claims 71, 72, and 73, corresponding to previously presented claims 51, 52, and 53, respectively, with certain clarifications.

Similarly, Applicant has added new claims 74 and 75, corresponding to previously presented claims 61 and 62, respectively.

Applicant believes that new claims 71-75 are allowable, and respectfully requests allowance of these claims.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612-373-6951) to facilitate prosecution of this application.

Applicant has enclosed a check in the amount of \$84.00 to cover the fee for adding additional claims. If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 10 day of July, 2003.

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